IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

IN RE: AFLIBERCEPT PATENT

LITIGATION MDL No. 1:24-MD-3103

This Document Relates to:

No. 1:23-cv-94

MEMORANDUM OPINION AND ORDER DENYING REGENERON'S MOTION TO STRIKE SAMSUNG BIOEPIS'S INEQUITABLE CONDUCT AFFIRMATIVE DEFENSE AND TO DISMISS ITS INEQUITABLE CONDUCT COUNTERCLAIM [ECF NO. 472]

Pending before the Court is Plaintiff Regeneron Pharmaceuticals, Inc.'s ("Regeneron") Motion to Strike Samsung Bioepis's Inequitable Conduct Affirmative Defense and to Dismiss Its Inequitable Conduct Counterclaim [ECF No. 472].

In its Answer, Samsung Bioepis Co., Ltd. ("SB") argues for the infectious unenforceability of U.S. Patent No. 11,975,045 ("the '045 patent"), among other patents asserted against it here. SB's Answer at 291-97, 381-87 (ECF No. 457). Specifically, SB alleges that at least Dr. George Yancopoulos, sole named inventor of the '045 patent, withheld certain material Regeneron documents ("the Withheld References") during prosecution of U.S. Patent Nos. 10,130,681 ("the '681 patent") and 9,254,338 ("the '338 patent"), both parents of the '045 patent, with intent to deceive the United States Patent Office. *Id.* SB thus argues that this alleged

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 $^{^{\}rm 1}$ Regeneron's Motion to Strike challenges only SB's allegations relating to the '045 patent.

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inequitable conduct renders the '045 patent unenforceable under the doctrine of infectious unenforceability. Id.

motion to strike, Regeneron challenges In its SB's allegations only on the ground that the Withheld References were disclosed during prosecution of the '045 patent, thus "cur[ing] any potential nondisclosure in the application resulting in the '045 patent[.]" Regeneron's Motion to Strike at 8 (ECF No. 472). SB does not dispute that the references were thusly disclosed. SB's Response in Opposition at 7-8 (ECF No. 479). However, SB argues that whether Regeneron successfully cured any inequitable conduct is at least a factual inquiry inappropriate for disposition at the pleading stage. Id. at 16-17. For the reasons stated below, the Court agrees with SB.

Regeneron's argument that disclosure of withheld references in a subsequent continuation application is sufficient for cure as a matter of law is in clear contradiction with the reasoning of the Federal Circuit in Cordis Corp. v. Bos. Sci. Corp, 188 F. App'x 984, (Fed. Cir. 2006) (nonprecedential). The accused infringer in that case alleged, as SB does here, infectious unenforceability of an asserted patent based on the withholding of material references during prosecution of a parent application where those references were later disclosed during the prosecution of the asserted patent. Id. at 988-89.

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In Cordis Corp., the district court below had found infectious unenforceability after a bench trial on that issue, specifically reasoning that the later disclosure did not cure the original inequitable conduct. Id. Rather than dismissing this possibility as a matter of law, as Regeneron would have this Court do here, the Federal Circuit remanded for further explanation of the court's factual findings on the issue, directing it to consider the test for cure given in Rohm & Haas Co. v. Crystal Chem. Co., 722 F.2d 1556, 1572-73 (Fed. Cir. 1983), a test Regeneron urges this Court not to use (Regeneron's Reply at 4-5 (ECF No. 482)). Cordis Corp., 188 F. App'x at 988-89. The Court need not here decide whether Rohm & Haas is appropriate for evaluating SB's allegations. The Federal Circuit's reasoning in Cordis Corp. is sufficient to rebut Regeneron's single argument that its later disclosure alone cured any potential inequitable conduct as a matter of law.

Regeneron discusses and quotes from *Cordis Corp.* only in response to SB's reliance on it and only to summarize the Federal Circuit's reasoning without distinguishing it, then going on to argue by analogy from the subsequent district court opinion *Cordis Corp. v. Bos. Sci. Corp.*, 641 F. Supp. 2d 353, 359 (D. Del. 2009). Regeneron's Reply at 7 (ECF No. 482). However, that opinion was issued after a bench trial was held on unenforceability and partially relied on the fact that the patent examiner specifically noted that he had reviewed the withheld reference, which has not

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been alleged by Regeneron here. Cordis Corp., 641 F. Supp. 2d at 359. More generally, Regeneron's only cited case with comparable facts decided at the pleading stage, added only in its Reply [ECF No. 482], was decided by another district court over ten years before Cordis Corp. See Applied Materials, Inc. v. Advanced Semiconductor Materials Am. Inc., 1994 WL 270714 (N.D. Cal. Apr. 1994), aff'd sub nom., Applied Material, Inc. v. Advanced

Regeneron has thus failed to show that SB's allegation of infectious enforceability is ripe for disposition at the pleading stage, and its motion to strike [ECF No. 472] is **DENIED**.

Semiconductor Materials Am., Inc., 104 F.3d 376 (Fed. Cir. 1996).

It is so **ORDERED.**

The Clerk is directed to transmit copies of this Order to counsel of record.

DATED: September 8, 2025

Tom 8 Klur

THOMAS S. KLEEH, CHIEF JUDGE NORTHERN DISTRICT OF WEST VIRGINIA